REMARKS

I. Claim Status

Claims 1-6 are currently pending. Claims 3-6 have been withdrawn from reconsideration. Claim 7 has been canceled without prejudice. Claim 1 has been amended herein. That claim is supported in the original specification and claims at, for example, claim 7 and page 3, line 1. Accordingly, no new matter is added herein.

II. 35 U.S.C. § 112, Second Paragraph Rejection

The Office rejected claims 1 and 2 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Office Action at 3. Without in any way conceding the propriety of this rejection and solely in an effort to expedite prosecution, Applicants have amended claim 1 herein to include the limitation recited in now canceled claim 7. Because the Office has implied that this limitation renders the claim definite (Office Action at 4), this rejection is rendered moot.

Moreover, Applicants have further defined the patient population to include human patients.

III. 35 U.S.C. § 102(b) Rejection

The Office rejected claims 1, 2, and 7 under 35 U.S.C. § 102(b) as allegedly anticipated by Puurunen, K. et al., "An α_2-adrenergic antagonist, atipamezole, facilitates behavioral recovery after focal cerebral ischemia in rats," *Neuropharmacology* (2001) 40:597-606 ("Puurunen"). Office Action at 4.

Applicants respectfully traverse this rejection. Claim 1 recites

> A method for inhibiting the development of epilepsy, comprising administering an effective amount of an alpha2-adrenoceptor antagonist to a human patient at risk of developing epilepsy, wherein said risk of developing epilepsy

is caused by head trauma, brain ischemia, infection, or neurosurgical operation.

That claim is not expressly or inherently anticipated by Puurunen. In particular, Puurunen relates solely to ***rat*** studies using atipamezole or enriched-environment conditions after focal cerebral ischemia was induced. Puurunen does not expressly anticipate the claims because the patient population presently recited, human patients, is not explicitly disclosed in Puurunen. In other words, the patient populations of Puurunen and those encompassed within the present claims do not overlap.

Moreover, Puurunen is entirely silent with respect epilepsy in general. In fact, there is no disclosure that the rats studied in any group developed epilepsy. Thus, for this second reason, Puurunen does not expressly anticipate the present claims.

To establish an inherent anticipation rejection, the Office would have to show some concrete technical feature that treating rats following cerebral ischemia would necessarily and inevitably result in a method according to the present claims. However, such a technical link cannot be established. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is ***necessarily*** present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, ***may not be established by probabilities or possibilities***. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, (Fed. Cir. 1999) (emphasis added). *See also* M.P.E.P. §2112.

The extrinsic evidence does not make clear that the claimed method would necessarily and inevitably result from Puurunen. First, Puurunen does not administer atipamezole to humans. Second, as mentioned above, Puurunen is wholly silent with

respect to epilepsy. And, third, Puurunen highlights the differences between animal and human stroke patients, suggesting that atipamezole's disclosed effect in rats may not be the same in human patients. *See* Puurunen at page 604, top of first column. As pointed out, human stroke patients recover over weeks and months, sometimes with residual damage, whereas rats have a remarkable ability to recover from strokes. Such uncertainty fails to rise to the "necessarily and inevitably" standard for inherent anticipation because one of ordinary skill in the art would not have been able to establish that the missing descriptive information was necessarily present. For these reasons, this rejection should be withdrawn.

Furthermore, Puurunen does not render obvious the presently pending claims. In particular, obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*, 9 F.2d 1531 (Fed. Cir. 1993). *See also* M.P.E.P. 2141.02. Because Puurunen is entirely silent with respect to epilepsy and human patients were not studied, an obviousness rejection over Puurunen could not be sustained.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: August 12, 2009

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